SEP 2 8 2005

K052593

510(k) Summary
for
FUSION Curing Light

1. SPONSOR

DentLight Inc.
4404 Breckinridge Blvd. Suite 500
Richardson, TX 75082

Contact Person: Richard Liu
Tel: 972-889-8857

Date Prepared: September 9, 2005

2. DEVICE NAME

Proprietary Name: FUSION curing light
Common/Usual Name: dental curing light
Classification Name: ultraviolet activator for polymerization (872.6070)

3. PREDICATE DEVICES

Dentsply SmartLite PS Pen-Style LED curing light (K041372)
Southern Dental Industries Radii (K030568)

4. DEVICE DESCRIPTION

The DentLight's FUSION Curing Light is a battery-powered cordless unit designed for curing VLC materials whose initiator systems are sensitive to light in the 440-480nm wavelength range of the visible spectrum. The unit is based on blue LED (light emitting diode) technology for light generation in the desired wavelength and Li-Ion rechargeable batteries.

The FUSION Curing Light includes:

- A handpiece with a focusing lens focusing light emitted from a single LED probe tip and controlled by built-in control electronics
- A detachable rechargeable battery unit
- A base unit that plugs into main power as the handpiece stand
- An eye shield and disposable cap at probe tip
- Disposable disinfectant barrier sleeves on the probe tube

5. INTENDED USE

The FUSION LED curing light is indicated for curing camphorquinone-based visible light cured (VLC) dental materials.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANDTIAL EQUIVALENCE

The FUSION LED Curing Light is substantially equivalent to K041372 and K030568 in intended use and operation.

FUSION Curing Light offers multiple curing programs for photopolymerization of dental resins and activation of bleaching materials. These program differ in the intensity of the light delivered and the length of the light exposure. The operational principles of the proposed and predicate devices are identical. The operator chooses the appropriate program by a selection of the push buttons.

The major difference between the proposed FUSION Curing Light and the predicate curing lights is the intensity of the light power delivered, the longer range of curing distance, size and weight. The increased light intensity of the proposed FUSION Curing Light allows the resin curing and tooth whitening agent activation to be conducted at faster speed. The longer range of curing distance enables more flexibility for operators. The size and weight is a benefit to constant patient operations and counter space.

7. PERFORMANCE TESTING AND COMPLIANCE

The following testing was conducted to evaluate the functionality performance of the proposed FUSION Curing Light:

- Optical Power Testing
- Resin curing time
- Curing range
- Optical wavelength
- Software and hardware verification and validation

The FUSION is designed to comply with electrical safety and electromagnetic compatibility and will comply with electrical safety requirement established by IEC 60601 and 60601-1-2.

We believe the similarity of the FUSION LED Curing Light to the legally marketed predicate devices and the performance data provided support the safety and effectiveness of the FUSION LED Curing Light for the indicated use.

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K052593 Third Party Organization: Reg Tech Services, LLC

Third Party's Primary Reviewer(s): Mark Job

ODE/OIVD Division: DAGID Branch/Team: DEDB

Section 2 – 510(k) Decision

Third party recommendation: SE ✓ NSE ____ Other (specify): ____

ODE/OIVD final decision: SE ✓ NSE ____ Other (specify): ____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	✓		
b. Extent of pre-submission consultation with ODE/OIVD division	✓		
c. Organization and format of review documentation	✓		
d. Determination of 510(k) administrative completeness (screening review)	✓		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	✓		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	✓		
g. Rationale for conclusions and recommendation	✓		
h. Use of guidance documents and standards	✓		
i. Resolution of 510(k) deficiencies and FDA requests for additional information	✓		
j. Scope of reviewer expertise and use of consulting reviewers	✓		
k. Other (specify):			

Comments (explanation of ratings/issues): ____

Section 4 – ODE/OIVD Assessor Information

Assessed by: [signature] MSQ Date: 9/20/05 Tel. No.: 301-827-5283

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2005

DentLight, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K052593
Trade/Device Name: FUSION Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: September 19, 2005
Received: September 21, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for CKL

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052593

Device Name: FUSION Curing Light

Indications For Use:

The FUSION Curing Light is a dental curing light that is intended for photopolymerization of dental resins, restorative composite materials, and orthodontic brackets, bonding, and sealing that are photo-polymerized in the 440 – 480 nm wavelength range.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K052593